K031978

JUL 2 1 2003

EXHIBIT 2

Amplaid –
Biomedical division of Amplimedical S.p.A. (Amplifon Group)
Via Donizetti, 12 - 20090
Assago - Milan (Italy)
Tel. +39 02 45790303
Fax. +39 02 45790340
Contact: Giovanni Rollier, CEO
June 24, 2003

510(k) Summary of Safety and Effectiveness

1. **Identification of the Device:**
   Proprietary-Trade Name: Amplaid A756
   Classification Name: Auditory Impedance Tester 77ETY
   Common/Usual Name: Admittance Meter

2. **Equivalent legally marketed devices** This product is similar in design and function to the AMPLAID A724 and A728 ADMITTANCE METERS (K992370)

3. **Indications for Use (intended use)** The Amplaid A756 Screening Admittance Meter can

- Evaluate middle ear functions such as otitis media, glue ear, eardrum scar tissues, perform myringotomy status, ossicular chain discontinuity ear canal volume, otosclerosis, stapes fixation.
- Perform Acoustic reflex test.
- Determine acoustic reflex threshold
- Perform reflex decay test.

The unit is intended for use by a qualified/trained audiologist on both adult and pediatric subjects for measurement of acoustic impedance.

4. **Description of the Device:** The Amplaid A756 Screening ADMITTANCE METER performs plane and compensated tympanometry; Programmed and manual stimuli for ipsilateral and contralateral acoustic reflex; Automatic reflex threshold; and Decay measurements.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicates that the new device is as safe and effective as the predicate device.

6. Substantial Equivalence Chart

Characteristic	Predicate K992370 Amplaid A724 –A728	Amplaid A756
Intended Use:	Clinical auditory impedance testing applications	Screening audiometry impedance testing applications
Technical characteristics		
Physical characteristics:		
Computer interface	RS232 Bi-directional	SAME
Display	Built-in liquid crystal	SAME
Control interface	Built-in keyboard	SAME
Size/weight	19.6"w x 16"d x 8"h 18.8 lbs.	14' x 11" x 7" 7.7 lbs.
Energy Source:	115/230 Vac, ± 10%, 50-60 Hz (100 va)	SAME (40 va)
Hardcopy Output:	Built-in Thermal printer	SAME
Standards and Safety characteristics:		
Audiometric:	Performance Standards **IEC 61027 (1993):** Instruments for the measurement of aural acoustic impedance/admittance **ANSI S3.39(1987)**:Specifications for Instruments to Measure Aural Acoustic Impedance and Admittance (Aural Acoustic Immittance); **IEC 60645-1**: Audiometers - Part 1: Pure-tone audiometers **ANSI S3.6 (1996):** Specification for audiometers; **EN ISO 389 (1995):** Acoustics – Standard reference zero for the calibration of pure-tone air conduction audiometers	SAME
Electrical safety:	EN 60601-1 Class I Type BF (1990); EN 60601-1/A1 (1993); EN 60601-1/A2 (1995); EN 60601-1/A13 (1996) EMC: EN 60601-1-2 (1993)	EN 60601-1 Class I Type B (1990); EN 60601-1/A1 (1993); EN 60601-1/A2 (1995); EN 60601-1/A13 (1996) EMC: EN 60601-1-2 (1993)

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of Amplaid. that the Amplaid A756 is safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 1 2003

Amplaid
c/o Daniel Kamm, P.E.
Regulatory Engineer
P.O. Box 7007
Deerfield, IL 60015

Re: K031978
Trade/Device Name: Amplaid A756 Screening Admittance Meter
Regulation Number: 21 CFR 874.1090
Regulation Name: Auditory impedance tester
Regulatory Class: Class II
Product Code: ETY
Dated: June 24, 2003
Received: June 26, 2003

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number K031978

Device Name: Amplaid A756 Screening Admittance Meter

Indications for Use: The Amplaid A756 Screening Admittance Meter can

1. Evaluate middle ear functions such as otitis media, glue ear, eardrum scar tissues, perform myringotomy status, ossicular chain discontinuity ear canal volume, otosclerosis, stapes fixation.
2. Perform Acoustic reflex test.
3. Determine acoustic reflex threshold
4. Perform reflex decay test.

The unit is intended for use by a qualified/trained audiologist on both adult and pediatric subjects for measurement of acoustic impedance.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K031978

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)